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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL, ACTION ON SMOKING AND HEALTH, NATIONAL MEDICAL ASSOCIATION, and AMERICAN MEDICAL ASSOCIATION,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; U.S. FOOD AND DRUG ADMINISTRATION; ROBERT CALIFF, in his official capacity as Commissioner of the U.S. Food and Drug Administration; CENTER FOR TOBACCO PRODUCTS; and BRIAN KING in his official capacity as the Center for Tobacco Products, Director,

Defendants.

Case No. 4:24-cv-1992-HSG

BRIEF OF R.J. REYNOLDS TOBACCO COMPANY AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Date: September 12, 2024
Time: 2:00 p.m
Judge: The Hon. Haywood S. Gilliam, Jr.
Place: Oakland, Courtroom 2, 4th Floor

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INTRODUCTION

In 2022, the U.S. Food and Drug Administration ("FDA") proposed the single most dramatic regulatory action regarding cigarettes in American history: a ban on menthol cigarettes, which constitute about one-third of the cigarette market and are used by millions of consumers. Unsurprisingly, as one of the defendants recently put it, the proposed rule "garnered historic attention" and prompted "an immense amount of feedback, including from various elements of the civil rights and criminal justice movement." Secretary Xavier Becerra, *Secretary Becerra Statement on the Proposed Menthol Cigarette Rule* (Apr. 26, 2024), https://tinyurl.com/3dpfn8bu ("Becerra Statement"). The vigorous and often critical response to the rule has made it "clear that there are still more conversations to have," which "will take significantly more time." *Id*. Plaintiffs now ask this Court to short-circuit those conversations and require defendants to issue the ban. Their arguments fail, and their complaint should be dismissed, for two independent reasons.

First, plaintiffs have not adequately alleged Article III standing. In fact, their sole theory of standing—which is that defendants' failure to ban menthol cigarettes is forcing plaintiffs to divert resources from other projects—was firmly and unanimously rejected by the Supreme Court this Term in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) ("*AHM*"). A simple comparison of the standing allegations in the First Amended Complaint with the Court's decision in *AHM* demonstrates that this suit cannot proceed.

Second, plaintiffs have not adequately alleged that defendants are legally required to issue the rule. Indeed, their position is fundamentally illogical. As already mentioned, defendants are currently in the process of assessing whether the rule would benefit the public or whether—as many civil rights and criminal justice advocates fear—it would actually *injure* the public health, with African American communities bearing the brunt of the harm. Nevertheless, plaintiffs insist that defendants are already under an obligation to issue the rule, because *they have already decided* that the rule would benefit the public (the very question they are currently considering). This position makes no sense, and is at war with the relevant statutory scheme as well as with broader principles of administrative law. This Court should dismiss the complaint.

STATEMENT OF THE ISSUES

1. Whether plaintiffs have adequately alleged Article III standing.

2. Whether plaintiffs have adequately alleged that FDA "unreasonably delayed" or "unlawfully withheld" the issuance of the proposed menthol ban.

STATEMENT OF FACTS

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA"). The TCA empowered the Secretary of Health and Human Services to adopt regulations for tobacco products—referred to as "tobacco product standards"—"if the Secretary finds that a tobacco product standard is appropriate for the protection of public health." 21 U.S.C. § 387g(a)(3). In making this finding, the Secretary is required to consider "all … information submitted" by the public, including "the countervailing effects of the tobacco product standard …, such as the creation of a significant demand for contraband." *Id.* § 387g(b)(2); *see also id.* § 387g(a)(3)(B)(i) (listing additional issues that the Secretary must consider when making such a finding).

In May 2022, pursuant to this authority, FDA published a notice of proposed rulemaking that would ban menthol as a flavor in cigarettes. *Tobacco Product Standard for Menthol in Cigarettes*, 87 Fed. Reg. 26,454 (May 4, 2022). In the public comment period that followed, FDA received an enormous number of comments from a variety of commenters, including amicus curiae R.J. Reynolds Tobacco Company ("Reynolds"). *See Tobacco Product Standard for Menthol in Cigarettes*, REGULATIONS.GOV, https://tinyurl.com/mry5tftc (rulemaking docket indicating that FDA received over 175,000 comments on the proposed menthol rule). Many of these comments focused on whether banning menthol cigarettes would satisfy the statutory standard: that is, whether a menthol ban actually would be "appropriate for the protection of public health" ("APPH"). Reynolds, along with many civil rights leaders and criminal justice reform advocates, offered a number of reasons to think that a menthol rule would *not* be APPH, including that it would create a thriving illicit market for menthol cigarettes and subject African American communities to

increased prosecutions, arrests, and negative law enforcement interactions.[1] On October 13, 2023, FDA transmitted the menthol rule to the Office of Information and Regulatory Affairs ("OIRA") for regulatory review. OIRA is a division of the Office of Management and Budget ("OMB"), which in turn is part of the Executive Office of the President. OIRA is the "repository of expertise concerning regulatory issues" within the executive branch, and its mission is to "provide guidance to agencies … in regulatory planning." Exec. Order No. 12,866 § 2(b) (Sept. 30, 1993) (Regulatory Planning and Review). Pursuant to Executive Order 12,866, OIRA reviews all proposed regulations that are considered economically "significant." *Id.* § 6(a). The goal of OIRA review is to "provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency." *Id.* § 6(b).

The menthol rule currently remains under review at OIRA. As part of the process, there have been over one hundred meetings between agency officials and various stakeholders on the proposed rule. *See* OIRA, *EO 12866 Meetings Search Results*, https://tinyurl.com/yeyj9pdn. These included several meetings with civil rights and criminal justice reform groups opposed to the rule, including a meeting that was attended by defendants Becerra and Califf, as well as senior White House officials. *See, e.g.*, OIRA, *View EO 12866 Meeting 0910-AI60*, https://tinyurl.com/bdfv5n3y (November 20, 2023 meeting with National Organization of Black Law Enforcement Executives); OIRA, *View EO 12866 Meeting 0910-AI60*, https://tinyurl.com/mpa2ybxc (December 6, 2023 meeting with Drug Policy Alliance); OIRA, *View EO 12866 Meeting 0910-AI60*, https://tinyurl.com/bdd4hmm2 (January 1, 2024 meeting with Law Enforcement Action Partnership).

[1] *See, e.g.*, Comment from RAI Services Company, Dkt. No. FDA-2021-N-1349-175111 (Aug. 1, 2022), https://tinyurl.com/r4uxzn9x ("Reynolds Comment"); Comment from National Organization of Black Law Enforcement Executives, Dkt. No. FDA-2021-N-1349-175322 (Aug. 3, 2022), https://tinyurl.com/2a34wz95; Comment from Ben Crump (on behalf of Civil Rights Trial Lawyers Association), Dkt. No. FDA-2021-N-1349-175701 (Aug. 3, 2022), https://tinyurl.com/3df96htc; Comment from Drug Policy Alliance, Dkt. No. FDA-2021-N-1349-175179 (Aug. 3, 2022), https://tinyurl.com/3kzwz6re; Comment from The Sentencing Project, FDA-2021-N-1349-172456 (July 29, 2022), https://tinyurl.com/59zvukkw; Comment from National Action Network, Dkt. No. FDA-2021-N-1349-91860 (June 17, 2022), https://tinyurl.com/4rbpwyvd.

These discussions are still ongoing. Secretary Becerra said as much in a recent statement regarding the rule: "This rule has garnered historic attention and the public comment period has yielded an immense amount of feedback, including from various elements of the civil rights and criminal justice movement. It's clear that there are still more conversations to have, and that will take significantly more time." Becerra Statement, *supra*.[2]

On April 2, 2024, plaintiffs filed this suit. They allege that, by failing to issue the menthol rule, defendants have "unlawfully withheld or unreasonably delayed" agency action in violation of the Administrative Procedure Act ("APA"). FAC ¶¶ 167–175 (citing 5 U.S.C. §§ 555(b) & 706(1)).

ARGUMENT

Under Federal Rule of Civil Procedure 12(b)(1), a complaint must be dismissed if the court lacks subject matter jurisdiction over the plaintiffs' claims. The burden of establishing subject matter jurisdiction rests on the plaintiffs. *Kokkonen v. Guardian Life. Ins. Co*., 511 U.S. 375, 377 (1994). If the plaintiffs cannot meet this burden, the court must dismiss without proceeding further. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998).

Here, the complaint must be dismissed for two reasons. First, plaintiffs' sole theory of Article III standing was just rejected by the Supreme Court. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024) ("*AHM*"); *see also Maya v. Centex Corp*., 658 F.3d 1060, 1067 (9th Cir. 2011) (explaining that, where plaintiffs have failed to plead Article III standing, their complaint must be dismissed for lack of subject matter jurisdiction). Second, plaintiffs have failed to identify any action that defendants were legally required to take. *Alvarado v. Table Mountain Rancheria*, 509

[2] This statement by Secretary Becerra is not mentioned in the First Amended Complaint because it was made after the First Amended Complaint was filed. *See* Pls.' Admin. Mot. to Consider Whether Cases Should Be Related at 4, 4:20-cv-04012-KAW (N.D. Cal. Apr. 29, 2024) (quoting the statement and noting that it was made "hours after Plaintiffs had filed their First Amended Complaint"); Pls.' Mot. for Admin. Relief at 3, ECF No. 25 (similar). However, this court is free to take judicial notice of this statement under Federal Rule of Evidence 201 because it is a matter of public record that is not subject to reasonable dispute. *Khoja v. Orexigen Therapeutics, Inc*., 899 F.3d 988, 999 (9th Cir. 2018) ("[A] court may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment." (citation omitted)); *Applied Underwriters, Inc. v. Lara*, 530 F. Supp. 3d 914, 923-24 (E.D. Cal. 2021) ("Courts routinely take judicial notice of … information on government websites." (internal citations omitted)), *aff'd on other grounds*, 37 F.4th 579 (9th Cir. 2022). Indeed, as noted, plaintiffs themselves have already quoted the statement in this litigation.

F.3d 1008, 1019–20 (9th Cir. 2007) (explaining that, where plaintiffs have failed to identify "a *discrete* agency action that [the agency] is *required to take*," a claim for agency action "unlawfully withheld or unreasonably delayed" must be "dismissed for lack of jurisdiction"). In particular, they cannot show that defendants have either unreasonably delayed, or unlawfully withheld, the menthol rule.

I. PLAINTIFFS' SOLE THEORY OF STANDING WAS RECENTLY REJECTED BY THE SUPREME COURT.

"At the pleading stage, a plaintiff must clearly allege facts demonstrating each element of Article III's standing requirements." *Lunn v. City of Los Angeles*, 629 F. Supp. 3d 1007, 1012 (C.D. Cal. 2022) (cleaned up); *see Barnum Timber Co. v. EPA*, 633 F.3d 894, 899 (9th Cir. 2011). Here, plaintiffs allege standing only pursuant to a "diversion of resources" theory that the Supreme Court squarely rejected in a recent decision. Accordingly, the complaint must be dismissed.

A. Plaintiffs claim that they are injured by defendants' failure to issue the menthol rule because it forces them to divert resources they would otherwise use for other purposes. In particular, AATCLC and ASH claim an injury in the form of being "force[d]" to continue spending on advocacy in response to FDA's purported inaction, and that but for this spending, they could expend their "resources and efforts to advancing … other organizational goals." FAC ¶¶ 24, 30. Similarly, NMA claims to be injured because defendants' inaction makes its advocacy efforts more difficult. FAC ¶ 35. Specifically, NMA alleges that "Defendants' unlawful conduct hinders the efforts of the NMA and its members to promote smoking cessation, and forces them to divert resources that could be used for other health policies." *Id.*[3]

The Supreme Court recently rejected precisely this sort of theory in *AHM*. There, a group of pro-life medical associations and individual physicians challenged FDA's decision to ease restrictions on mifepristone, an abortion drug. 602 U.S. at 373–74. One of their theories of standing was that FDA's decision to expand access to mifepristone had "impaired" the medical associations' "ability to provide services and achieve their organizational missions," and imposed injury in the

[3] There are no specific allegations regarding the standing of the last plaintiff, AMA. *See* FAC ¶¶ 36–38.

form of "incurring costs to oppose FDA's actions" "to the detriment of other spending priorities." *Id.* at 394. For example, the FDA's action caused the medical organizations "to conduct their own studies on mifepristone" in order to "better inform their members and the public about mifepristone's risks." *Id.* at 370. It also caused them to expend resources on "citizen petitions to FDA," as well as "public advocacy and public education." *Id.* The medical associations argued that, under *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), "standing exists when an organization diverts its resources in response to a defendant's actions." *AHM*, 602 U.S. at 395.

The Court firmly and unanimously rejected this theory. It explained that an organization that has not suffered a concrete injury caused by defendant's action "cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action." *Id.* at 394. If it were otherwise, the Court held, a plaintiff could "manufacture its own standing" in almost any case. *Id.*

That holding applies squarely here, because plaintiffs' theory is indistinguishable from the theory put forward by the medical associations in *AHM.* In particular, just like the medical associations, plaintiffs here allege an injury in the form of "incurring costs to oppose FDA's" failure to restrict access to a product "to the detriment of other spending priorities." *See id.* at 394. Even the particulars are very similar, given that each case involved an attempt by organizations to challenge FDA's failure to restrict third parties' access to a product, on the theory that the organizations had incurred costs to oppose FDA's policy instead of devoting financial resources to other initiatives. *Compare* FAC ¶ 24 (AATCLC alleging an injury in the form of "devoting resources and efforts to educate the public about the dangers of menthol cigarettes" when it "could instead be directing its resources and efforts to advancing the AATCLC's other organizational goals");¶ 30 (same for ASH); ¶ 35 (NMA alleging an injury in the form of "hinder[ed]" education and advocacy work and being "force[d] to divert resources that could be used for other health policies"), *with* Brief for Respondents at 43–44, *AHM*, 602 U.S. 367 (2024) (Nos. 23-235, 23-236), 2024 WL 811351 at *43–44 (alleging that FDA's actions "impaired Respondent organizations' ability to … achieve their organizational missions," "frustrate[d] and complicate[d]" their education and advocacy work, and forced them to "spend considerable resources on their public advocacy

and educational activities" "at the expense of other organizational efforts").

B. The Court in *AHM* also explained why *Havens Realty* provided no help to the medical associations (and similarly, to plaintiffs here). To begin, *Havens Realty* "was an unusual case, and [the] Court has been careful not to extend the *Havens* holding beyond its context." *AHM*, 602 U.S. at 396. And understandably so: an overly broad understanding of *Havens Realty* "would mean that all the organizations in America would have standing to challenge almost every federal policy that they dislike, provided they spend a single dollar opposing those policies." *Id.* at 395.

And the context of *Havens Realty* was very different than *AHM* (or this case). As the Court explained, the question in *Havens Realty* was "whether a housing counseling organization, HOME, had standing to bring a claim under the Fair Housing Act against Havens Realty, which owned and operated apartment complexes." *Id.* Havens Realty had engaged in a practice called "racial steering"—that is, it had provided HOME's black employees false information about apartment availability. *Id.* "Critically," HOME was not merely an issue-advocacy organization: it also "operated a housing counseling service." *Id.* As a result, receiving "false information about apartment availability" "directly affected and interfered with HOME's core *business* activities." *Id.* (emphasis added). The situation was akin to "a retailer who sues a manufacturer for selling defective goods to the retailer." *Id.* In other words, just like a retailer's business activities are hampered by receiving subpar goods, HOME's business activities were hampered by receiving bad information.

The medical associations in *AHM* could not take advantage of *Havens Realty* because they had not alleged anything similar; FDA's actions simply did not have a direct impact on their "*businesses*." *Id*. (emphasis added). It is just the same here. Defendants' failure to promulgate the menthol rule has no *direct* impact on plaintiffs' businesses, akin to palming off bad goods on a retailer or bad information on a housing counseling service. Instead, plaintiffs here are simply asserting that they will incur costs in seeking to offset the impact of the government's decision (to date) not to ban the sale of a product to third parties. This is *precisely* the kind of effort to "spend

[their] way into standing" that *AHM* conclusively forecloses. *Id.* at 394.[4] Accordingly, plaintiffs have failed to allege standing and their complaint must be dismissed.[5]

II. PLAINTIFFS' "UNREASONABLY DELAYED" CLAIM FAILS.

The APA is a limited waiver of sovereign immunity. 5 U.S.C. § 704. Courts therefore lack subject matter jurisdiction over challenges seeking to compel agency action that the agency is not legally required to take. *See, e.g.*, *San Luis Unit Food Producers v. United States*, 709 F.3d 798, 803–04 (9th Cir. 2013); *Alvarado*, 509 F.3d at 1019–20. As discussed below, plaintiffs have not identified any action defendants are legally required to take, and therefore this court lacks subject matter jurisdiction over their complaint.[6]

Plaintiffs' first theory is that agency action has been "unreasonably delayed" under 5 U.S.C. § 706(1) (or not performed "within a reasonable time" under 5 U.S.C. § 555(b)). FAC ¶ 168. The Ninth Circuit decides such claims under the framework articulated by the D.C. Circuit in *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) ("*TRAC*"). *Indep. Mining Co. v. Babbitt*, 105 F.3d 502, 507 (9th Cir. 1997).

The *TRAC* inquiry proceeds in two steps. The first step "is necessarily to determine whether the agency is required to act, that is whether it is under a duty to act." *In re A Cmty. Voice*, 878 F.3d 779, 784 (9th Cir. 2017) (citing *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 n.1 (2004) ("*SUWA"*)). If the agency has a duty to act, then the court moves on to the second step: analyzing the six "*TRAC* factors" to decide whether the agency's delay is "so egregious as to warrant mandamus." *TRAC*, 750 F.3d at 79. Failure at either step means that the claim fails. *In re A Cmty.*

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[4] Another key difference between *Havens Realty* and this case is that *Havens Realty* involved a suit between private parties, where standing concerns are less acute than in a suit seeking to compel government action. *See Spann v. Colonial Vill., Inc.*, 899 F.2d 24, 30 (D.C. Cir. 1990) (Ginsburg, R.B., J.) ("Plaintiffs are private actors suing other private actors, traditional grist for the judicial mill. Their suit does not raise the [standing and separation-of-powers] concerns that may arise when a public agency or officer is sued to achieve change in a government policy.").

[5] Because *AHM* resolves the standing question in this case, there is no need to consult prior Ninth Circuit precedent (which would be overruled to the extent inconsistent with *AHM*). But, as the government explains, plaintiffs would lose under that earlier precedent in any event. *See* Defs' Mot. to Dismiss 14–17, ECF No. 27.

[6] As the government notes, alternatively, this court could dismiss the complaint for failure to state a claim on the same grounds under Federal Rule of Civil Procedure 12(b)(6). *See* Defs' Mot. to Dismiss 10–11, 20–22, ECF No. 27.

Voice, 878 F.3d at 786. Here, plaintiffs have failed to meet their burden at either step, and their unreasonable delay claim should be dismissed.

A. FDA HAS NO DUTY TO ISSUE THE MENTHOL BAN.

The final menthol rule is currently under review at OIRA. This review has taken longer than originally expected because, as Secretary Becerra recently explained, it is necessary to have "more conversations" about whether the rule is advisable in its current form, in light of the "historic attention" and "immense amount of feedback" the rule has received, "including from various elements of the civil rights and criminal justice movement." Becerra Statement, *supra*.

In other words, defendants are currently in the process of assessing whether, in their view, the rule would benefit the public and should go forward, particularly in light of civil rights and criminal justice concerns raised by the rule. Plaintiffs insist, however, that defendants have a legal *duty* to short-circuit this process and promptly issue the rule. And the reason defendants are under this obligation, plaintiffs insist, is that defendants *have already decided* that the rule would benefit the public health (the very question they are currently considering). This startling theory makes no sense at a high level, and (as discussed below) it does not improve upon closer examination.

1. <u>The FDA statements that plaintiffs cite do not constitute an APPH determination.</u>

A court may only compel agency action "where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." *SUWA*, 542 U.S. at 64. The relevant legal obligation must be unambiguous, and an unreasonable delay claim can proceed only where plaintiffs have shown that the agency has "a clear, certain, and mandatory duty" to act, *Vaz v. Neal*, 33 F.4th 1131, 1136 (9th Cir. 2022) (citation omitted), that is "so clearly set forth that it could traditionally have been enforced through a writ of mandamus," *Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 923, 932 (9th Cir. 2010); *see also In re Nat'l Nurses United*, 47 F.4th 746, 752 (D.C. Cir. 2022) (legal duty to act must be "crystal-clear," "incontrovertible[,] and not a matter within the agency's discretion").

Plaintiffs claim that such a clear statutory duty can be found in 21 U.S.C. § 387g(d)(1), which—they assert—requires defendants to promulgate a tobacco product standard if three

conditions are met: (1) the Secretary has published a proposed rule and the comment period has closed, (2) the Secretary has considered comments and any Tobacco Products Scientific Advisory Committee ("TPSAC") report, and (3) the Secretary has determined that the standard would be APPH. FAC ¶¶ 12, 171–73. As discussed below, this interpretation of the statute is incorrect. *See infra* Part II.A.4. But the Court need not reach that question, because the third condition is not satisfied. That is, plaintiffs have failed to identify a determination by the Secretary that the standard would be APPH. This is because they point solely to statements made by FDA *prior* to the comment period, when any such determination would necessarily have to be made *after* the comment period.

a. The text of § 387g(d) and the basic structure and purpose of notice-and-comment rulemaking demonstrate that any APPH determination would have to take place *after* the comment period. Start with the statutory language. Section 387(d)(1) kicks in only "[a]fter the expiration" of the comment period for the notice of proposed rulemaking, as well as "after consideration of comments" on the proposed rule. 21 U.S.C. § 387g(d)(1). At that point, it is up to the Secretary to decide whether the rule is APPH. If the rule is *not* APPH, the Secretary is directed to "publish a notice terminating the proceeding for the development of the standard." *Id.* § 387g(d)(1)(A)–(B). If the rule *is* APPH, the Secretary is directed to promulgate it. *Id.* In other words, the order of operations is quite clear: first, the comment period; then, consideration of comments and any TPSAC report; then, consideration of whether to make an APPH finding; then promulgation of either the rule or a notice terminating the proceeding.

This statutory language is consistent with the general principle that any statement in a notice of proposed rulemaking is necessarily tentative. *Pub. Citizen, Inc. v. Trump*, 297 F. Supp. 3d 6, 25 (D.D.C. 2018) (explaining that a notice of proposed rulemaking "reflects an agency's preliminary assessment" and "in no way binds the agency to promulgate a final rule if further reflection, or changed circumstances, persuade the agency that no regulatory change is warranted" (cleaned up)). Indeed, it is odd to treat a notice of proposed rulemaking as making a "determination" of any kind, let alone one that commits the agency to act. If that were so, then the entire purpose of notice-and-comment rulemaking would be vitiated, because the agency would lose its ability to change its

mind in response to comments. *Alameda Health Sys. v. Ctrs. for Medicare & Medicaid Servs.*, 287 F. Supp. 3d 896, 919 (N.D. Cal. 2017) ("The point of notice-and-comment rulemaking is that public comment will be considered by an agency and the agency may alter its action in light of those comments." (citing *Hall v. EPA*, 273 F.3d 1146, 1163 (9th Cir. 2001))). For example, the D.C. Circuit has declined to compel agency action on the basis of conclusions reached by the agency prior to the notice-and-comment process. The court explained that, if the agency *were* bound by such earlier conclusions, "there would be little to be gained by undertaking the rulemaking process mandated by the [statute]." *In re Nat'l Nurses United*, 47 F.4th at 754. After all, the very "purpose of that process is to allow public input as the agency considers a health and safety problem and fashions the appropriate regulatory solutions." *Id.* It is just the same here.

Indeed, an agency acts *unlawfully* if it approaches the comment period with an "unalterably closed mind," as plaintiffs insist FDA must do here. *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979). In light of these rudiments of notice-and-comment rulemaking, it scarcely makes sense to say that the APPH determination was made *before* comments were submitted or considered.

b. And yet, that is precisely what plaintiffs say. In alleging that the APPH determination has been made, they point only to statements made by FDA at the notice of proposed rulemaking stage or earlier. Specifically, in the original complaint, plaintiffs asserted the Secretary has made the APPH determination since "at least May 2022," when the agency issued the notice of proposed rulemaking. Compl. ¶¶ 13, 143, 146. In doing so, plaintiffs identified the pages of the notice of proposed rulemaking that purportedly made the determination. Compl. ¶¶ 146 (citing 87 Fed. Reg. 26,455, 26,458, 26,461–62, 26,469–85). In the First Amended Complaint, plaintiffs moved the date the Secretary supposedly made the APPH determination even earlier, to "April 29, 2021," the date when FDA responded to their citizen petition. FAC ¶¶ 13, 129. Here too, plaintiffs point to specific statements in FDA's response to the citizen petition that they assert constituted an APPH determination. FAC ¶ 129. All of these statements occurred at the notice of proposed rulemaking stage or earlier.

The only reference to any purported *post*-comment period APPH determination is in

paragraph 159 of the First Amended Complaint, which asserts without explanation that, by February 1, 2023, the Secretary had determined that the menthol rule "was still appropriate for the protection of the public health." FAC ¶ 159. However, that paragraph offers no basis for the assertion, and it certainly does not identify any statement by the defendants that could qualify as an APPH determination. Such a "conclusory allegation[]" is not sufficient to plausibly allege that a APPH determination has been made. *Navajo Nation v. U.S. Dep't of the Interior*, 876 F.3d 1144, 1163 (9th Cir. 2017). Alternatively, as the government points out, this allegation can be rejected as factually false based on "publicly available facts" outside the complaint. *See* Defs' Mot. to Dismiss 18–19, ECF 27 (citing *Am. Diabetes Ass'n v. U.S. Dep't of the Army*, 938 F.3d 1147, 1151 (9th Cir. 2019)). And in any event, this allegation would fail for reasons explained in the next subsection. Accordingly, plaintiffs have not identified an APPH determination, and the complaint should be dismissed.

2. Defendants have not made, and as a matter of law, could not yet have made, an APPH determination.

As noted, plaintiffs have not pointed to any post-comment period statements by defendants that purportedly reflect an APPH determination. Nor could they. After all, Secretary Becerra—the official who is statutorily responsible for making such a determination—recently released a statement *explicitly declaring* that he has *not* made a determination about the menthol rule. Becerra Statement, *supra.* As he has explained, further consultation with civil rights groups and criminal justice advocates is necessary to determine whether the menthol rule should go forward. *Id.* And indeed, Secretary Becerra has been actively involved in ongoing deliberations about the menthol rule. For example, he has participated in the OIRA process, including by attending an OIRA meeting between senior White House officials and civil rights leaders. *See* OIRA, *View EO 12866 Meeting 0910-AI60*, https://tinyurl.com/bdfv5n3y. In other words, Secretary Becerra is still considering whether the rule, far from protecting public health, will instead exacerbate racial health inequalities and lead to heavy-handed and inequitable enforcement. It is nothing short of bizarre to insist that he has *already determined* that the rule is APPH.

And there is no basis for such an assertion. As previously noted, the menthol rule is still

going through the OIRA process. Any initial conclusions the agency reaches prior to completion of the OIRA process are necessarily tentative. After all, the OIRA process is designed to shed further light on the policy issues presented by a proposed rule. OIRA review is intended to ensure that agencies "assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating" and select the regulatory approach that "maximize[s] net benefits (including potential economic, environmental, public health and safety, and other advantages …)." Exec. Order No. 12,866 § 1(a) (Sept. 30, 1993) (Regulatory Planning and Review). Moreover, by facilitating public participation from "a range of interested or affected parties, including underserved communities," the OIRA process allows "regulatory action [to be] informed by input from interested or affected communities." Exec. Order No. 14,094 § 2 (Apr. 6, 2023) (Modernizing Regulatory Review). In short, the OIRA process provides feedback to the agency—particularly from the communities most affected by the proposed regulation—and ensures it takes relevant factors into account. In doing this, the OIRA process *helps the Secretary assess* whether the rule is APPH.

By contrast, plaintiffs' view would render the OIRA process completely useless. According to plaintiffs, defendants are already bound to issue the rule as-is, regardless of what feedback they receive from OIRA and other stakeholders. For example, under plaintiffs' view, even if the OIRA meetings made it utterly clear to defendants that the menthol rule, as written, would severely *harm* the public health, defendants would be powerless to change their mind. But there is no evidence that Congress intended § 387g(d) to so profoundly disrupt the regulatory review process, and courts have been reluctant to interfere with this executive branch prerogative. *Env't Def. Fund v. Thomas*, 627 F. Supp. 566, 571 (D.D.C. 1986) (declining to enjoin OMB review because, among other reasons, it would be "an unwarranted intrusion into discretionary executive consultations"); *Pub. Citizen Health Rsch. Grp. v. Tyson*, 796 F.2d 1479, 1507 (D.C. Cir. 1986) ("OMB's participation in [this] rulemaking presents difficult constitutional questions concerning the executive's proper rule in administrative proceedings …. Courts do not reach out to decide such questions."); *see In re City of Virginia Beach*, 42 F.3d 881 (4th Cir. 1994) (rejecting an unreasonable delay claim against FERC because the application at issue was being reviewed by the Secretary of Commerce).

The only way to harmonize § 387g(d) with the OIRA process is thus to reach the commonsense conclusion that the Secretary does not make an APPH determination at least until the OIRA process is complete. Accordingly, no such determination has been made—and, as a matter of law, no such determination could have been made—here.

3. In any event, FDA lacks the delegated authority to make an APPH determination, at least at this time.

Plaintiffs' attempt to identify an APPH determination also fails because they point exclusively to statements made *by FDA*, not by Secretary Becerra himself. Section 387g(d) provides that the Secretary shall promulgate a regulation if (among other things) "*the Secretary* determines that the standard would be [APPH]." 21 U.S.C. § 387g(d)(1) (emphasis added); *see* 21 U.S.C. § 321(d) (making clear that "the Secretary" here refers to "the Secretary of Health and Human Services").

Nevertheless, although plaintiffs allege that "the Secretary" has made an APPH determination, *see* FAC ¶¶ 159, 172, they exclusively point to statements made *by FDA* as the purported APPH determination. (Indeed, as noted above, the Secretary has expressly stated that he has not made a decision as to whether the rule should proceed. Becerra Statement, *supra.*) But a determination made *by FDA* could function as a determination made *by the Secretary* only if it was made pursuant to a valid delegation of authority from the Secretary to FDA. And as explained below, no such delegation has been made here.

To be sure, the Secretary has generally delegated to FDA "the authority vested in the Secretary to issue all regulations of the FDA." *Food and Drug Administration; Delegation of Authority*, 86 Fed. Reg. 49,337, 49,337 (Sept. 2, 2021). And that delegation is consistent with Congress's direction that the Secretary generally should regulate tobacco products "through the [FDA] Commissioner." 21 U.S.C. § 393(d)(2). But that delegation is not limitless, and two of the limitations are independently dispositive here.

First, the Secretary has expressly reserved the authority to approve certain categories of FDA regulations, including those that "present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices,

tobacco products, or other subjects of regulation." 86 Fed. Reg. 49,337.[7] The proposed menthol ban easily qualifies under this exception as it "present[s] highly significant public issues" concerning the "availability" or "marketability" of "tobacco products." *Id.* As such, the Secretary has retained authority to approve the menthol ban, and FDA cannot *obligate* the Secretary to issue the menthol ban (or else his approval authority would be circumvented). In other words, if an APPH determination by FDA would bind the Secretary to issue the ban, then FDA lacks the delegated authority to make that determination (and it has to be made by the Secretary himself). This conclusion is consistent with Secretary Becerra's approach to this rule—as described above, he has taken an active role in the OIRA process and has expressly stated that he has not yet decided whether the rule should move forward.

Second, FDA's delegated authority must be "exercised in accordance with the Department's applicable policies, procedures, and guidelines." 86 Fed. Reg. 49,337. One of those policies is the executive order imposing the OIRA process, which applies to all executive agencies, and which has been expressly recognized by HHS policy. Exec. Order No. 12,866 § 3(b) (Sept. 30, 1993) (Regulatory Planning and Review); *Find Rules by Operating Divisions*, HHS (last updated June 5, 2019), https://tinyurl.com/2zc2ctvy (noting that, under the executive order, OIRA "must review" significant rules and "the Department's division(s) issuing the rule will consult with OIRA through the Executive Secretariat to obtain the appropriate clearances"). Thus, if making an APPH determination at this point would defeat the OIRA process—as, according to plaintiffs, it would—then such a determination would not be consistent with HHS's policies, and FDA lacks the authority to make the determination.

In short, the APPH determination must be made *by the Secretary*, and plaintiffs have identified no such determination.

4. <u>Even if the Secretary had made an APPH determination, there would be no duty to issue the menthol ban.</u>

As demonstrated above, plaintiffs' understanding of the statute has odd and indefensible

[7] Plaintiffs specifically acknowledge this limitation on the delegation to the Commissioner in their First Amended Complaint. FAC ¶ 40.

implications. Plaintiffs insist, in effect, that simply by making statements in support of the yet-to-be-proposed menthol rule—before the comment period—defendants have locked themselves into an obligation to promulgate the menthol rule, regardless of what they went on to learn in the crucial comment period and OIRA review phases of the rulemaking process. This would not only vitiate the notice-and-comment process as well as the OIRA review process, but it would intrude severely on the agency's discretion, including the decision *not* to promulgate a final rule. *Ass'n of Oil Pipe Lines v. FERC*, 83 F.3d 1424, 1432 (D.C. Cir. 1996) ("An agency is free to adjust *or abandon* [its] proposals in light of public comments or internal agency reconsideration without having to start another round of rulemaking." (internal quotation marks omitted and emphasis added)); *see also Rowell v. Andrus*, 631 F.2d 699, 702 n.2 (10th Cir. 1980) (noting that "[a]t the point of publication of the proposed rule the agency is, of course, not bound to the issuance of the rule in any exact form," and the agency is free to "scuttle the whole proposal"). Under plaintiffs' approach, it is hard to understand how FDA could ever propose a product standard (a process which necessarily involves making an argument in favor of that standard), without irreversibly committing itself to issuing that standard. This will not do.

As also demonstrated above, this unpalatable conclusion can be avoided simply by recognizing that an APPH finding has not yet been made (and indeed could not yet have been made). But if this Court rejects that view, it will have to consider whether plaintiffs are right that once the statutory "preconditions" are met, defendants are *obligated* to issue the final rule (whether they think doing so is a good idea or not). The answer to that question is no.

Plaintiffs' theory turns entirely on the word "shall." FAC ¶¶ 12, 171–73. To be sure, that word "usually connotes a requirement." *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016). But as the Supreme Court has recognized, this is not always the case, and it is less likely to be the case when government discretion is implicated. *See Town of Castle Rock v. Gonzales*, 545 U.S. 748, 761 (2005) (declining to interpret the word "shall" as mandatory in the context of "deep-rooted … law-enforcement discretion").

The Ninth Circuit has applied this principle in the context of agency decisionmaking in an opinion that is on all fours with this case. *Sierra Club v. Whitman*, 268 F.3d 898 (9th Cir. 2001).

Sierra Club begins by recognizing that "the use of 'shall' is not conclusive." *Id.* at 904. It goes on to explain that, "[p]articularly when used in a statute that prospectively affects government action"—as the statute in this case does—"'shall' is sometimes the equivalent of 'may.'" *Id.* at 904 (citing *Richbourg Motor Co. v. United States*, 281 U.S. 528, 534 (1930)). Applying these principles, *Sierra Club* held that, despite the use of the word "shall," the Clean Water Act did not impose a *duty* on EPA to issue compliance orders or bring enforcement actions upon finding a violation of the statute. *Id.* at 904–05. It gave two primary reasons for that conclusion, both of which squarely apply here.

First, it pointed to the "structure" of the statute. *Id.* Although the Clean Water Act sometimes uses the word "shall" in describing the Administrator's enforcement authority, it otherwise provides that the Administrator is "authorized" to issue compliance orders or bring enforcement actions. *Id.* at 904. This "language of authorization," *Sierra Club* held, reflected a "congressional intent to give the Administrator these options, not to require their use in all instances." *Id.* It is just the same here. The word "shall" comes from § 387g(d), which addresses promulgation of product standards. 21 U.S.C. § 387g(d). But § 387g(a)—the main provision setting forth the Secretary's authority—states that the Secretary "may" adopt a tobacco standard "if" he has determined it would be APPH in light of enumerated statutory criteria. *Id.* § 387g(a)(3); *see id.* § 387g(b). This is "language of authorization," not obligation, and reflects congressional intent to give the Secretary discretion in adopting tobacco product standards. *Sierra Club*, 268 F.3d at 904. Thus, like the Clean Water Act, the Tobacco Control Act *authorizes* the adoption of tobacco product standards, but does not mandate them whenever an APPH determination is made.

Second, *Sierra Club* looked to legislative history. It found that, notwithstanding the Clean Water Act's use of "shall," legislative history confirmed that Congress had intended for the Administrator to enjoy enforcement discretion. *Id.* The same is true here. The House Committee Report, which plaintiffs cite throughout their complaint, reflects the Committee's belief that, given the numerous "open questions" related to regulating menthol cigarettes, the TCA should "*authorize[]* the Secretary to ban or modify the use of menthol in cigarettes *based on scientific evidence*." H.R. Rep. No. 111-58, pt. 1, at 39 (2009) (emphases added). The open questions

Congress had in mind included questions related to the "disproportionate prevalence of menthol cigarettes among African Americans" and "uncertainty about the potentially negative consequences" of a menthol ban—in other words, the very same questions that Secretary Becerra is now considering. *Id.* In short, the legislative history cuts against the mandatory reading of "shall" here at least as strongly as it did in *Sierra Club*.

Ultimately, then, even if plaintiffs are correct that an APPH determination has been made, they are wrong to suggest that this imposes a duty on defendants to issue the final rule.

B. FDA HAS NOT "UNREASONABLY DELAYED" THE MENTHOL BAN.

Even if plaintiffs could establish that FDA has a duty to issue the menthol ban, they cannot show that the agency's delay in doing so is "so egregious as to warrant mandamus." *TRAC*, 750 F.3d at 79.

1. Fundamentally, any delay cannot be laid at the feet of defendants because they have submitted the final rule to OIRA and are now awaiting the completion of OIRA review. In other words, they are not currently causing any delay, and they lack final say over the ongoing OIRA process. Any delay at this point should be attributed to OIRA and, more broadly, OMB and the Executive Office of the President—which are not defendants here. This alone is a dispositive threshold objection to plaintiffs' arguments. In an analogous case, the Fourth Circuit rejected an unreasonable delay claim where a different agency was reviewing the regulation plaintiffs said was delayed. *In re City of Virginia Beach*, 42 F.3d at 881. The case involved an unreasonable delay claim against FERC, which responded by pointing to (among other things) the fact that the application at issue was being reviewed by the Secretary of Commerce, per standard FERC procedure. And the Fourth Circuit accepted that explanation, noting that the delay was "justified by application of established agency procedure." *Id.* at 886. The same logic applies here: it is established FDA procedure to submit rules to OIRA review, and it is that established procedure that is currently causing the delay.

2. In any event, this delay is more than reasonable under the so-called "*TRAC* factors." In assessing whether a delay is unreasonable, courts consider the following:

> (1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order that agency action is "unreasonably delayed.

Indep. Mining Co., 105 F.3d 507 & n.7 (quoting *TRAC*, 750 F.2d at 80). There is no per se rule on whether a delay is unreasonable, and the *TRAC* factors are not "ironclad" but offer "useful guidance." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008). Courts typically consider *TRAC* factors one and two together. *Milligan v. Pompeo*, 502 F. Supp. 3d 302, 317 (D.D.C. 2020). The first—the rule of reason—has been called the "most important." *Core Commc'ns*, 531 F.3d at 855. It asks "whether the agency's response time … is governed by an identifiable rationale." *Ctr. for Sci. in the Pub. Int. v. FDA*, 74 F. Supp. 3d 295, 300 (D.D.C. 2014). And the second—whether Congress has provided a timetable—"may supply content for th[e] rule of reason." *TRAC*, 750 F.2d at 80.

As an initial matter, there is no statutory timeline for promulgating a menthol rule, which weighs strongly in defendants' favor on *TRAC* factors one and two. *Cobell v. Norton*, 240 F.3d 1081, 1096 (D.C. Cir. 2001) ("An agency's own timetable for performing its duties in the absence of a statutory deadline is due 'considerable deference.'"). Additionally, while plaintiffs never identify what they think the delay period is or why it is unreasonable, they seem to be faulting FDA for not releasing the rule by its original internal deadline of August 2023. FAC ¶ 160. But even assuming that the ongoing "delay" could be attributed to defendants (which, as noted, it cannot), and even assuming that FDA should have been expected to release the rule by August 2023 (though plaintiffs do not explain why that is so), the "delay" since then has been less than a year. This is not even remotely long enough to constitute unreasonable delay under the caselaw. *See, e.g., United Steelworkers of Am. v. Rubber Mfrs. Ass'n*, 783 F.2d 1117, 1120 (D.C. Cir. 1986) (per curiam) (fourteen-month delay in rulemaking "does not seem … facially unreasonable"); *Sierra Club v. Thomas*, 828 F.2d 783, 799 (D.C. Cir. 1987), *abrogated in part on other grounds by statute*

(nearly three-year delay in rulemaking "can hardly be considered unreasonable" given the "complexity of the issues" and the "highly controversial nature of the proposal").

A few months' delay attributable to OIRA's review of the rule is not egregious compared to the years of agency inaction courts have typically found required before compelling agency action.[8] As the D.C. Circuit has cautioned, "the APA is patient." *Env't Def. Fund v. EPA*, 922 F.3d 446, 457 (D.C. Cir. 2019). Accordingly, at least in the absence of statutory deadlines, an agency "need not address all regulatory obligations 'in one fell swoop,'" and courts should avoid second-guessing agency efforts to prioritize among them. *Id.* (citation omitted).

Plaintiffs try to get around all of this—including the lack of a statutory timeline—by cobbling together an argument that Congress wanted FDA to address menthol "quickly," based on a fragment of legislative history, and a separate TCA provision directing TPSAC to study menthol "[i]mmediately upon" its establishment. FAC ¶¶ 4–5, 7, 47–50, 56–58; *see* 21 U.S.C. § 387g(e)(1). But courts have rejected similar invitations to infer a mandatory timeline based on legislative history in "the absence of any comparable mandate in the statute's text." *Consumer Fed'n of Am. v. U.S. Consumer Prod. Safety Comm'n*, 883 F.2d 1073, 1078 (D.C. Cir. 1989). Nor is there any basis for suggesting that *FDA* must act immediately *as to the rule* simply because *TPSAC* was required to act immediately *with respect to a report.* If anything, the TPSAC provision indicates that Congress knew how to impose a timeline when it wanted to do so. *See Russello v. United States*, 464 U.S. 16, 23 (1983) (courts generally presume that "Congress acts intentionally and purposely in the disparate inclusion or exclusion" of statutory language). And as noted, the *TRAC* analysis is forgiving; indeed, plaintiffs have lost under the *TRAC* factors even where agencies have failed to comply with specific statutory deadlines. *See, e.g., In re Barr Lab'ys, Inc.*, 930 F.2d 72, 73 (D.C. Cir. 1991). As such, plaintiffs' efforts to conjure a statutory timeline from legislative history and indirectly related provisions are futile.

3. Plaintiffs may ask for these considerations to be tossed aside because "human health and

[8] *See, e.g.*, *In re Pub. Emps. for Env't Resp.*, 957 F.3d 267, 274 (D.C. Cir. 2020) (nineteen-year delay); *In re Core Commc'ns, Inc.*, 531 F.3d 849, 857 (D.C. Cir. 2008) (seven-year delay); *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 420 (D.C. Cir. 2004) (seven-year delay); *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 554 (D.C. Cir. 1999) (after eight-year delay, ordering agency to produce timetable for final rulemaking).

welfare are at stake." *TRAC*, 750 F.2d at 80. But the ban has been delayed precisely because there is a vigorous debate as to whether the ban will promote the public health and welfare. Again, the Secretary has publicly stated that the rule is delayed because there are "still more conversations to have," including with "various elements of the civil rights and criminal justice movement," regarding the mountain of feedback the rule has received. Becerra Statement, *supra.* In other words, HHS *is in the process of attempting to determine*, in consultation with civil rights and criminal justice reform leaders, whether the rule would promote the public health and welfare. It would make no sense to short-circuit that process *on the assumption* that the rule would benefit the public.

The Third Circuit has made this point very clearly. It has explained that an appeal to the impact of an agency action on human health "presupposes … that the evidence before the agency sufficiently demonstrates that delay will in fact adversely affect human health to a degree which necessitates a priority response." *Oil, Chem. & Atomic Workers Union v. OSHA*, 145 F.3d 120, 123 (3d Cir. 1998). Accordingly, it declined to "tell the Secretary how to do her job" in light of "varying data and differing interpretations" of the relevant risks. *Id.* at 123–24. It is just the same here.

Indeed, in reality, the rule would only harm public health. As Reynolds explained in its comment on the proposed rule, the ban would not reduce smoking rates, but would lead to a variety of harmful unintended consequences. *See generally* Reynolds Comment, *supra*. For example, a robust longitudinal study about the impact of the European Union's menthol cigarette ban confirms that FDA's ban would not reduce smoking rates (and may even increase daily smoking). *Id.* at 4, 25–32. And the ban is likely to have severe and harmful countervailing effects on public health, including (but not limited to) the creation of a significant illicit market for contraband cigarettes, an increase in product tampering and "self-mentholation," consumer confusion, and a negative impact on vulnerable populations. *Id.* at 9–11, 78–145. Of course, the Court need not here reach the question of whether the menthol ban would help or harm public health. It is enough for present purposes to note that there is a robust debate over this issue, and therefore plaintiffs cannot circumvent the ordinary *TRAC* calculus.

III. PLAINTIFFS' "UNLAWFULLY WITHHELD" CLAIM FAILS.

Plaintiffs also argue that FDA has "unlawfully withheld" agency action under 5 U.S.C. § 706(1). FAC ¶ 168. This argument fails for the same reasons discussed above, as well as additional reasons.

To begin, this claim suffers from the same basic problem as plaintiffs' "unreasonably delayed" claim: there is no statutory duty to issue the menthol ban. Similar to an "unreasonably delayed" claim, a court can compel agency action "unlawfully withheld" only where there is "a specific, unequivocal command" placed on the agency to take a "discrete agency action," and the agency has failed to take that action. *SUWA*, 542 U.S. at 63–64; *see also Vietnam Veterans of Am. v. CIA*, 811 F.3d 1068, 1081 (9th Cir. 2016) (this type of relief "is restricted to discrete actions that are unequivocally compelled by statute or regulation"). And as explained above, defendants are under no duty to issue the menthol ban because the Secretary has made no APPH determination.

This claim also suffers from the separate defect that, even if there were a clear statutory duty to issue the menthol ban, there is certainly no clear statutory duty to do it within any specific time frame. An "unlawfully withheld" claim thus cannot support the relief plaintiffs seek—all of which is predicated on the theory that the menthol rule has to be promulgated within a certain time. For example, plaintiffs seek an order that the rule be issued within a "reasonable timeframe." FAC ¶ 49. But as noted, there is no such requirement in the TCA, so plaintiffs cannot possibly obtain that relief under the "unlawfully withheld" rubric. Similarly, plaintiffs seek a declaration that defendants are in violation of the TCA. *Id.* But again, the "unlawfully withheld" argument at most could establish that the TCA requires the menthol ban to be issued; it does not supply any basis for declaring that FDA is currently in violation of the TCA by not having issued it already. In short, the relief plaintiffs seek requires them to show that FDA has *taken too long* to issue the rule, and the "unlawfully withheld" argument is not sufficient to demonstrate that. Instead, any such relief can only be based on an "unreasonably delayed" claim—which also fails in this case, as discussed above.

CONCLUSION

For the reasons set forth above, Reynolds respectfully requests the Court grant defendants' motion to dismiss.

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